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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,173	07/21/2005	Vibeke Nissen	0114229/0556833	9550

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FROST BROWN TODD, LLC
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EXAMINER

DEES, NIKKI H

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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05/26/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Office Action Summary	Application No. 10/520,173	Applicant(s) NISSEN, VIBEKE	
	Examiner Nikki H. Dees	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-12,14-19 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-12,14-19 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>29 Oct. 2008, 11 March 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 11, 2009, has been entered.
2. Claims 1-6, 8-12, 14-19, and 28-32 are currently pending in the Application.

Claim Objections

3. Claim 16 objected to because of the following informalities: claim 16 lacks a final punctuation mark. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10, 12, 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 10 and 12 claim a chewing gum tablet "substantially free" of certain ingredients. It is unclear what amounts of the claimed ingredients may, or may not, be present in the chewing gum tablet to be considered "substantially free" of said ingredients. For purposes of examination, the presence of less than about 1% by weight of the chewing gum tablet of the claimed ingredients will be considered to meet the limitation "substantially free."

7. Claim 16 claims sweeteners comprising about 5 to about 95% by weight of the chewing gum. It is unclear if applicant is referring to the weight of the entire chewing gum tablet or the chewing gum center. For purposes of examination, it will be interpreted as about 5 to about 95% by weight of the chewing gum tablet.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-6, 8-12, 14-19 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (4,753,805) in view of Hinzpeter et al. (5,643,630).

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10. Cherukuri et al. teach compressed chewing gum tablets having a water content of about 2% and a method for making them. A chewing gum composition is prepared including gum base granules composed of natural and synthetic resin and elastomers in an amount ranging from 14 to 50 wt % (col. 6 lines 14-24), flavors in an amount ranging from 0.05 to 3 wt % (col. 8 lines 14-34), natural resins (e.g. rosin esters) including glycerol esters of polymerized rosin in an amount ranging from about 10 to 75 wt % (col. 6 lines 24-42), sweeteners ranging in an amount from about 0.001 to 90 wt % depending on the sweetener selected (col. 6 line 52-col. 7 line 21), plasticizer and active ingredients (col. 9 lines 14-29), and optionally wax (col. 7 lines 36-40). The amounts taught for these components substantially overlap with the amounts claimed by Applicants. The flavorings and active agents are mixed (teared) into the gum-base composition prior to compression (Example I; col. 8 lines 14-29).

11. The granules are compressed into tablets. Magnesium stearate is present in the compressed tablets as a lubricant (col. 5 lines 1-10). The lubricant is added following the granulation of the gum center (Example II). The lubricant aids in granulation by facilitating removal from the mold, reducing the wear on the dies and punches, and minimizing the potential for capping (col. 4 lines 34-60).

12. Regarding claim 6, Cherukuri et al. are silent as to the "improved and sticky" texture of the tablet resulting from the inclusion of the natural resin. However, as the invention of Cherukuri et al. comprises the same ingredients as claimed by Applicants in substantially similar amounts, this improved texture would have been expected to be

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present in the invention of Cherukuri et al. absent convincing arguments or evidence to the contrary.

13. Cherukuri et al. are silent as to the gum center being encapsulated by the barrier layer.

14. Hinzpeter et al. teach compressed tablets comprising a lubricant wherein the lubricant is deposited directly on the tableting machine to facilitate the production of tabletted materials and form a barrier layer on the tablet utilizing minimal amounts of lubricant (col. 1 lines 57-62). They teach their process as an improvement over the prior art, wherein the lubricants (e.g. magnesium stearate) were combined with the material to be compressed (col. 1 lines 33-40). Hinzpeter et al. teach their invention as an improvement of the prior art process as it requires less lubricant, requires less pressure for tableting, and reduces the wear on the compression tools (col. 2 lines 48-55). The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing of the tablets (col. 2 lines 20-24).

15. One of ordinary skill in the art at the time the invention was made wishing to improve the compressed tablet of Cherukuri et al. the process by which it was made by providing a barrier layer using less magnesium stearate or other lubricant, would have found it obvious to employ the tableting method of Hinzpeter et al. for tableting the chewing gum of Cherukuri et al. in order to provide a tabletted chewing gum with a barrier layer while requiring less lubricant and reducing the wear on the production equipment. The use of magnesium stearate as a barrier layer for tabletted materials, as taught by Hinzpeter et al., instead of mixing with the granulated chewing gum material

as taught by Cherukuri et al., would have been an obvious improvement of the prior art method at the time the invention was made. The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing process. It is noted that the limitation of the barrier layer being provided during the manufacturing process is considered to be a product by process limitation and does not determine the patentability of the chewing gum product. In any event, Hinzpeter et al teach forming the barrier layer during tableting.

16. Claims 1-6, 8-12, 14-19 and 28-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (EP 0 221 850) in view of Hinzpeter et al. (5,643,630).

17. Yang teaches compressed chewing gum tablets having a water content of about 2% and a method for making them. A chewing gum composition is prepared including gum base granules composed of natural and synthetic resin and elastomers (col. 8 lines 47-58)), flavors in an amount ranging from about 1 to 10 wt % (col. 10 lines 30-55), natural resins (e.g. rosin esters) including glycerol esters of polymerized rosin in an amount ranging from about 10 to 75 wt % of the gum base (col. 8 line 59-col. 9 line 13), sweeteners ranging in an amount from about 0.001 to 98 wt % depending on the sweetener selected (col. 9 lines 29-65), plasticizer and active ingredients (col. 7 line 58-col. 8 line 19), and optionally wax (col. 9 lines 14-26). The amounts taught for these components substantially overlap with the amounts claimed by Applicants. The flavorings and active agents are mixed (teared) into the gum-base composition prior to compression (col. 11 lines 28-37).

18. The granules are compressed into tablets. Magnesium stearate is present in the compressed tablets as a lubricant. The lubricant aids in the tableting by facilitating removal from the mold, reducing the wear on the dies and punches, and easing the ejection of the tablet from the die (col. 10 lines 3-23).

19. Regarding claim 6, Yang is silent as to the "improved and sticky" texture of the tablet resulting from the inclusion of the natural resin. However, as the invention of Yang comprises the same ingredients as claimed by Applicants in substantially similar amounts, this improved texture would have been expected to be present in the invention of Yang absent convincing arguments or evidence to the contrary.

20. Yang is silent as to the gum center being encapsulated by the barrier layer.

21. Hinzpeter et al. teach compressed tablets comprising a lubricant wherein the lubricant is deposited directly on the tableting machine to facilitate the production of tabletted materials and form a barrier layer on the tablet utilizing minimal amounts of lubricant (col. 1 lines 57-62). They teach their process as an improvement over the prior art, wherein the lubricants (e.g. magnesium stearate) were combined with the material to be compressed (col. 1 lines 33-40). Hinzpeter et al. teach their invention as an improvement of the prior art process as it requires less lubricant, requires less pressure for tableting, and reduces the wear on the compression tools (col. 2 lines 48-55). The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing of the tablets (col. 2 lines 20-24).

22. One of ordinary skill in the art at the time the invention was made wishing to improve the compressed tablet of Yang, and the process by which it was made, would

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have found it obvious to employ the tableting method of Hinzpeter et al. for tableting the chewing gum Yang in order to provide a tabletted chewing gum with a barrier layer while requiring less lubricant and reducing the wear on the production equipment. The use of magnesium stearate as a barrier layer for tabletted materials, as taught by Hinzpeter et al., instead of mixing with the granulated chewing gum material as taught by Yang, would have been an obvious improvement of the prior art method at the time the invention was made. The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing process. It is noted that the limitation of the barrier layer being provided during the manufacturing process is considered to be a product by process limitation and does not determine the patentability of the chewing gum product. In any event, Hinzpeter et al teach forming the barrier layer during tableting.

23. Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 1-6, 8-12, 14-19 and 28-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 and 34 of copending Application No. 10/520,387. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the barrier layer in the claims of 10/520,387 to either partially or fully encapsulate the claimed gum tablet simply depending upon desired results, consumer appeal and personal preference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 1-6, 8-12, 14-19 and 28-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 of copending Application No. 11/028,684 in view of Cherukuri et al or Yang. It would have been obvious to include magnesium stearate as an outer barrier layer in the gum tablets claimed in 11/028,684 since magnesium stearate is a conventional lubricant used in gum tablets, as evidenced by either secondary reference and since it would have been obvious to include the magnesium stearate as the outer layer of the tablets as set forth in the rejections *supra*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

27. Applicant's arguments with respect to the failure of Cherukuri et al. or Yang to teach compressed chewing gum tablets comprising a barrier layer as claimed have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 7:30 AM to 5:00 PM (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./
Examiner, Art Unit 1794
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794